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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/081,953	**Applicant(s)** HENNEN ET AL.	
	Examiner Stacy B. Chen	**Art Unit** 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 April 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: 17.
   Claim(s) rejected: 1-16 and 18-22.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:

The rejection of claims 1-3, 7-16 and 18-22 under 35 U.S.C. 102(b) as anticipated by Tokoro (US 5,080,895) is maintained for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily drawn to the following:

Applicant argues that independent claim 1 is directed to methods for causing treated animals to elicit a T-cell mediated immune response. Applicant argues that Tokoro neither expressly nor inherently describes a method for causing chickens to generate transfer factor that is present in their eggs. Tokoro is limited to exposing a chicken to certain antigens, not including Newcastle Disease Virus (NDV). The antigens disclosed in Tokoro are particular ETEC antigens that are not of the type that induce a T-cell immune response. Applicant argues that the antigens that Tokoro uses are not of the types that induce a T-cell immune response, which is required for real transfer factor to be present. The "transfer factor-like component" is not real transfer factor, evidenced by several literature references that support this statement, all of record.

Applicant points to the MPEP 2112 which explains that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result of characteristic. Applicant argues that a chicken would not necessarily be exposed to some antigen that would induce a T-cell response. Chickens are raised in controlled environments that prevent exposure of a chicken to any antigens, including Newcastle diseases virus. Applicant argues that Tokoro does not expressly or inherently describe that chickens must be exposed to any other antigens. Applicant points to Tokoro's teaching (col. 2, lines 54-60) that rats may be "germ-free", which implies a sterile environment. In response to Applicant's argument, the Office maintains that Tokoro's chickens were exposed to antigens that induced T-cell immune responses. The reason that chickens are immunized with Newcastle vaccine is that chickens are exposed to NDV. If chicken accommodations were sterile, then no vaccination would ever be required. The Office maintains that Tokoro's chickens were undoubtedly exposed to a pathogen at some point before laying eggs that induced an immune response. Unless Tokoro housed the chickens in a completely sterile environment, one would expect that Tokoro's chickens had had a T-cell immune response to some antigen. Tokoro's reference to germ-free rats is in no way limiting the environment of Tokoro's hens to sterile only. Further, the context in which the germ-free rats are mentioned is not directly related to the method and composition described by Tokoro. The comments are in reference to summarizing the prior art. One of ordinary skill in the art would recognize that Tokoro's chickens were at some point exposed to antigens that induce T cell immune responses, thus necessarily producing transfer factor.

Applicant argues that neither Tokoro or Kirkpatrick teach or suggest collecting eggs that have adequate transfer factor for transferring cellular immunity in vivo. In response to Applicant's argument, any amount of transfer factor is expected to transfer cellular immunity to a mammal. Cellular immunity in this context refers to the passing along of transfer factor molecules from the egg to the egg consumer. The consumer of Tokoro's eggs is expected to ingest transfer factor.

The rejection of claims 4-6 under 35 U.S.C. 103(a) as obvious over Tokoro in view of Kirkpatrick (US 5,840,700) is maintained for reasons of record. Applicant argues that one of ordinary skill in the art would not have had the benefit of hindsight that the claims and disclosure of the above-referenced application has provided to the Office, which is apparently the sole source of motivation for the assertion that one of ordinary skill in the art would have had motivated to combine teachings relating to obtaining transfer factor from mammalian tissues (Kirkpatrick) with teachings that relate to the presence of a non-transfer factor, transfer factor-like substance in eggs (Tokoro). Applicant argues that there is no motivation to combine Tokoro and Kirkpatrick. Applicant points out that Kirkpatrick is limited to teachings methods for purifying transfer factor that has been obtained conventionally, from the cells of mammals, while the teachings of Tokoro relate to methods for generating antibodies and a "transfer factor-like" component in eggs, with no mention that transfer factor is actually present in the eggs. Given this knowledge, one of ordinary skill in the art would not have been motivated to employ the transfer factor purification processes of Kirkpatrick on a composition, such as that disclosed in Tokoro, that is not known to include transfer factor.

Applicant also argues that the teachings of Kirkpatrick relate to a purified product that may be effectively administered to a treated animal non-orally, while the compositions of Tokoro are intended to be adminstered orally so that they can be used to treat intestinal pathogens. Applicant also argues that Tokoro plainly teaches that the presence of antibodies in the compositions disclosed therein are beneficial to treated animals, without providing data as to the benefits of the "transfer factor-like" component mentioned therein. Applicant argues that if the method of Kirkpatrick were employed on the composition of Tokoro, antibodies would be removed from that composition, negating any proven effect thereof in treating intestinal pathogens. Applicant also argues that one of ordinary skill in the art would have no reasonable expectation from the teachings or suggestions of Tokoro that transfer factor would or could have been collected from eggs. Thus, Applicant argues that one of ordinary skill in the art would have no reason to attempt to purify an extract of an egg obtained in accordance with teachings from Tokoro in the manner taught by Kirkpatrick, let alone any reason to expect that transfer factor could be purified in an amount adequate for transferring cellular immunity to a mammal in vivo.

In response to Applicant's arguments, one would have been motivated to purify Tokoro's tranfer factor-like substance away from molecules greater than 8 kD to obtain a purer product. Tokoro already purifies the substance from molecules of 10 kD. One of ordinary skill would have recognized that purification according to Kirkpatrick would work with Tokoro's composition because both references teach purification of immune components obtained from eggs, wherein the components are not antibodies/immunoglobulins, but function in passive tranfer of delayed-type hypersensitivity. Given this knowledge, one would have had a reasonable expectation of success that purification of Tokoro's composition would have yielded a product of greater purity.

Further, with regard to the presence of transfer factor in Tokoro's composition, given the method of production of the respective compositions of Tokoro and Kirkpatrick, transfer factor is expected to be in both compositions. Even if Tokoro does not purify the

composition further to exclude molecules of greater than 8 kD, the presence of transfer factor is expected. The obviousness rejection asserts that one would have arrived at the claimed invention even if one did not know transfer factor was present in the composition of Tokoro. If one were to try to obtain transfer factor-like substance from Tokoro, one would have followed Tokoro's teachings. It would have been obvious to further purifying the transfer factor-like substance (for reasons of record). The final product would be the same as Applicant's claimed invention. Therefore, the rejections are maintained for reasons of record.

Stacy B Chen 5/16/2006

Stacy B. Chen
Primary Examiner
TC1600